ZEPHIRAN® CHLORIDE AQUEOUS SOLUTION 1:750

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Sanofi-Synthelabo Inc.

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PRODUCT NAME: ZEPHIRAN® CHLORIDE AQUEOUS SOLUTION 1:750

SYNONYMS: Benzalkonium Chloride

#### 2. COMPOSITION/INFORMATION ON INGREDIENTS

#### **INGREDIENTS**:

Benzalkonium chloride, 0.13% CAS NUMBER: 8001-54-5 OSHA PEL: None established ACGIH TLV: None established

Purified Water, USP, >99.8% CAS NUMBER: 7732-18-5

#### HAZARDS IDENTIFICATION

**CAUTION:** Use only as directed.

#### POTENTIAL HEALTH EFFECTS:

Irritant to skin and eyes.

May be dangerous if swallowed.

ZEPHIRAN® CHLORIDE AQUEOUS SOLUTION 1:750 is supplied as a clear, colorless to slightly yellow liquid in bottles of 8 fluid ounces and 1 gallon.

## 4. FIRST AID MEASURES

In case of contact, immediately flush eyes thoroughly with running water for at least 15 minutes. Seek medical attention immediately.

In case of contact with skin and clothing, remove contaminated clothing and wash skin thoroughly with running water for at least 15 minutes. Use soap if available. Seek medical attention if irritation develops.

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#### **INGESTION**

In case of acute overdose by ingestion, seek immediate medical attention or contact the Poison Control Center for further instructions.

#### **INHALATION**

Not an expected route of entry.

#### NOTE TO PHYSICIAN

If ingested, marked local irritation of the gastrointestinal lining may occur. Administer several glasses of a mild soap solution, milk or egg white beaten in water. Gastric lavage is NOT recommended.

#### 5. FIRE FIGHTING MEASURES

#### FIRE AND EXPLOSION HAZARDS

This formulation is aqueous based and does not present any significant fire and explosion hazards.

#### EXTINGUISHING MEDIA

Carbon dioxide, dry chemical powder, water spray or foam.

#### **FIRE FIGHTING INSTRUCTIONS**

As in any fire, use pressure demand self contained breathing apparatus (SCBA) and protective clothing to prevent contact with skin and eyes. Use water spray to keep fire-exposed containers cool.

#### 6. ACCIDENTAL RELEASE MEASURES

Necessary personal protective equipment should be worn when cleaning up a spill [See Section 8].

Soak up contents of spilled material with an absorbent material. Carefully collect material and place in a properly labeled waste container for disposal. Wash area of spill to remove from surfaces. Wash thoroughly after handling.

## 7. HANDLING AND STORAGE

#### **HANDLING AND STORAGE PRECAUTIONS**

Store in original container in areas inaccessible to small children. Keep securely closed.

#### WORK/HYGIENE PRACTICES

Avoid contact with eyes, skin and clothing. Use local exhaust ventilation or respiratory protection for operations which generate aerosols. Wash thoroughly after handling.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **ENGINEERING CONTROLS**

General ventilation is recommended.

#### **EYE/FACE PROTECTION**

Avoid eye contact. Wear safety glasses with side shields or goggles.

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# **SKIN PROTECTION**

Avoid skin contact. Chemically impervious gloves must be worn.

#### RESPIRATORY PROTECTION

None normally required. However, a respiratory program that meets OSHA's 29CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions, such as generation of aerosols, warrant respirator usage.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

## **APPEARANCE**

Clear, colorless to slightly yellow liquid.

## BASIC PHYSICAL PROPERTIES

SOLUBILITY: Soluble in water

pH: Basic

#### 10. STABILITY AND REACTIVITY

#### **STABILITY**

Stable

#### INCOMPATIBLE MATERIALS

Strong oxidizing agents.

## HAZARDOUS COMBUSTION/DECOMPOSITION PRODUCTS

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and hydrogen chloride gas.

#### HAZARDOUS POLYMERIZATION

Will Not Occur.

#### 11. TOXICOLOGICAL INFORMATION

NOTE: In humans the toxic response produced varies widely with dose and concentration of the solution.

# **HUMAN CLINICAL STUDIES**

Zephiran Chloride in normally used concentrations has a low systemic and local toxicity, and is generally well tolerated. Ingestion of dilute solutions may cause irritation or gastrointestinal disturbances. A dose of 266 mg/kg produced diarrhea, esophageal damage, hallucinations and distorted perception. large potentially fatal doses are associated with gastrointestinal damage, low blood pressure, restlessness, confusion, muscle weakness, difficulty breathing, respiratory paralysis, kidney failure, convulsions, fluid in the lungs (pulmonary edema), and circulatory shock.

#### **ANIMAL STUDIES**

In rats and mice effects reported following oral dosing included decreased activity. In rats 250 mg/kg or greater produced distinct reddening of the tissue lining the stomach, sloughing of this tissue and bleeding. Following IP administration to rats ataxia (loss of coordination/imbalance), difficulty breathing, and ulceration or bleeding from the small intestine were reported. Convulsions were produced following IV administration to mice.

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#### ACUTE EFFECTS (SINGLE DOSE/EXPOSURE)

The values given in the table below refer to amount of active ingredient, **zephiran chloride**.

<b>Species</b>	Route	$LD_{50}$ (mg/kg)
Mouse	Intravenous (IV)	26
	Intraperitoneal (IP)	22 (minimum lethal dose)
Rat	IV	25 to 27
	IP	33 to 50
	Oral	350 to 690
Rabbit	IV	>10 (no deaths at this dose)
	Oral	>500 (no deaths at this dose)
	Subcutaneous	>50 (no deaths at this dose)
Guinea Pig	IP	10 to 20 (minimum lethal dose)
	Oral	>100 (no deaths at this dose)
		>500 (no deaths at this dose)

## EFFECTS OF REPEATED DOSES/EXPOSURES

In rats, 274 mg/kg for 2 years produced decreased food intake, decreased body weight gain or loss of weight, and death. In a 15 week dog study effects on body weight and death were produced. In dogs daily doses of 25 mg/kg continued for several weeks are lethal.

## EYE EFFECTS

The degree of irritation produced depends on the concentration of the solution which comes into contact with the eye. Zephiran chloride has been reported to produce severe eye irritation in humans, mild to severe irritation in rabbits, and severe irritation in monkeys. In rabbits, exposure to a 0.1% solution for 15 minutes produced severe injury with swelling, grayness of the cornea, and superficial desquamation of the conjunctival epithelium.

# **SKIN EFFECTS**

Solutions of 0.1% zephiran chloride or greater are irritating to skin and mucous membranes. Intermittent contact of substance with human skin has produced mild irritation. Application to rabbit skin produced moderate irritation.

#### **SENSITIZATION**

Not available. Some individuals may experience hypersensitivity to zephiran chloride products.

## REPRODUCTIVE AND DEVELOPMENTAL EFFECTS

Intervaginal application of 100 mg/kg produced post-implantation mortality and fetal death in rats. Doses of 200 mg/kg were associated with pre-implantation mortality.

#### CARCINOGENIC EFFECTS

Not classified as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

None available

#### 13. DISPOSAL CONSIDERATIONS

Dispose in accordance with local, state and federal regulations.

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## 14. TRANSPORT INFORMATION

Not regulated by USDOT as a hazardous material. Not regulated by IATA as a dangerous good.

# 15. REGULATORY INFORMATION

## U.S. FEDERAL REGULATORY INFORMATION

This product does not contain any ingredients which are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under Section 313 of EPCRA, (SARA Title III).

OSHA chemical hazards according to 29 CFR 1910.1200: Skin and eye irritant

## 16. OTHER INFORMATION

N/A = Not Applicable N/D = Not Determined ~ = Approximately Equal To

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